

EXHIBIT 51

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates to:

All Actions MDL No. 15-2666 (JNE/DTS)

DEPOSITION OF JONATHAN B. BORAK, M.D.

VOLUME I, PAGES 1 - 97

FEBRUARY 15, 2019

(The following is the deposition of
JONATHAN B. BORAK, M.D., taken pursuant to Notice of
Taking Deposition and Subpoena, via videotape, at the
Omni New Haven Hotel at Yale, 155 Temple Street, in
the City of New Haven, State of Connecticut,
commencing at approximately 11:14 o'clock a.m.,
February 15, 2019.)

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1 Q. Have you seen the raw data that the Jeans
2 study is based upon?

3 A. The only data that I have seen relates
4 ultimately back to that which underlay the McGovern
5 study, which is part of the Jeans study.

6 Q. Do you have the documents that were produced
7 today in front of you?

8 A. I'm sorry? Say it again.

9 Q. Do you have the documents that were produced
10 to me --

11 A. Yes.

12 Q. -- in front of you?

13 A. I have my set. Is that --

14 Q. You have your set.

15 A. I have my set.

16 Q. When you authored the Axline report, can you
17 please identify from your set what documents you had
18 available?

19 A. (Witness reviewing documents.)

20 Q. And just for the record, the date of your
21 Axline report is September 4th, 2018.

22 A. I --

23 Do you want me to read you off and tell you
24 what they are?

25 Q. Well when it relates to your opinions in --

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1 McGovern study. I brought with me a copy of a paper
2 by Refaie, R-E-F-A-I-E, at al, called Prevention of
3 peri -- Periprosthetic Joint Infection. I brought
4 with me a copy of a -- I think a -- probably a book
5 chapter by Jameson and Reed. And I've brought with me
6 the expert report of Professor Holford.

7 Q. So would it be fair enough that the
8 documents by Michelle Kuman and Dr. Augustine you did
9 not have by the time you authored your opinion in
10 Axline?

11 A. I was not aware of them at the time that I
12 authored my opinion in Axline.

13 Q. Who made you aware of the Jeans study?

14 MR. GOSS: Object to form.

15 A. I'm not sure. I periodically review the
16 literature. I have a librarian in my office who does
17 that periodically. So I would have been looking at,
18 if not monthly, then bimonthly searches on prosthetic
19 or periprosthetic joint infections and it might have
20 come up there, but it's also possible that it was sent
21 to me by the attorneys.

22 Q. And just so I understand you clearly, it's
23 your opinion that the Jeans study shows that MSSA
24 screening causes a reduction of MSSA infections.

25 A. That is my understanding, and I believe

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1 for the Jeans study. That's my real question.

2 A. The documents that I brought today all
3 directly or indirectly relate to the Jeans study and
4 that's why I brought them.

5 Now I've just sorted out those that I had
6 before September 4th and those that I acquired after
7 September 4th, and I brought one page which was
8 composed sometime at -- around then which was from the
9 Axline study.

10 Q. Fair enough.

11 So what documents did you have prior to
12 September 4th, 2018?

13 A. That I have brought with me.

14 Q. That relate to the Jeans study and your
15 opinions today.

16 A. Okay.

17 Q. Whether or not you brought with you or not.

18 I just want to know what is your basis on
19 the Axline. And I assume that if you didn't look at
20 it before September 4th, 2018 it wasn't the basis for
21 the opinions in the Axline opinion.

22 A. A very reasonable approach.

23 I brought with me a copy of the Jeans study.

24 Q. Yes.

25 A. I brought me -- with me a copy of the

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1 that's what the paper shows.

2 Q. So the paper shows causation, in your
3 opinion.

4 A. Causation of what?

5 Q. Of a reduction of MSSA infections.

6 A. The data, as presented, gives -- indicates
7 that implementation of MSSA screening reduced the
8 frequency or was at least associated with a reduction
9 in the frequency of MSSA infections.

10 Q. Now those are two key words, "association"
11 and "causation."

12 A. Yes.

13 Q. And you're familiar with those two words;
14 correct?

15 A. Yes.

16 Q. Is it your opinion that there is an
17 association with respect to MSSA screening in the
18 reduction of MSSA infections, or there was causation?

19 A. Are we --

20 I don't think you can conclude causation on
21 the basis of one study such as this.

22 Q. So you agree with me that the Jeans study
23 does not conclude causation with respect to MSSA
24 screening and its relationship with MSSA infections.

25 A. Yes, it does not prove causation.

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1 Q. And that is because it's a retrospective
2 study; correct?

3 A. No. It's because it's an observational
4 study.

5 Q. Observational study. But --
6 And it looked at the data retrospectively;
7 correct?

8 A. Whether they had looked at it
9 retrospectively or prospectively, it could have shown
10 association and not causation, given the nature of the
11 world.

12 Q. Given the nature of the?

13 A. World.

14 Q. And what do you mean by "the nature of the
15 world"?

16 A. What I mean is that observations --
17 observational studies are inherently, not by design,
18 experiments, and even though they look experimental,
19 they have uncertainties which can't be eliminated.

20 (Borak Exhibit 2 marked for
21 identification.)

22 (Discussion off the stenographic record.)

23 BY MR. ASSAAD:

24 Q. What's been marked as Exhibit 2 is your
25 report of September 4th, 2018 with respect to Nancy

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1 And attached to my report, which you pointed
2 out was 40 pages, was a very long list of references
3 which I have reviewed in a variety of contexts.

4 Q. It's 40 actually.

5 A. Well... Thank you. Okay.

6 So now we go back to 21. Yes, fine. That
7 is about -- That's correct.

8 Q. So paragraphs 21, 21a and 21b are your
9 opinions with respect to the Jeans study; correct?

10 A. Yes. The Jeans study is mentioned in each
11 of those paragraphs.

12 Q. Okay. And paragraphs 21a and 21b are
13 conclusions or opinions you draw from the Jeans study
14 as it relates to McGovern; correct?

15 A. I want to be as precise as I can. Bear with
16 me, I'm sorry, but. (Witness reviewing exhibit.)

17 Yes. There are actually conclusions in all
18 three paragraphs.

19 (Interruption by the reporter.)

20 Q. And that's based on your conclusions you're
21 drawing from the Jeans study; correct?

22 A. In the context, yes.

23 Q. Yes.

24 Have you --

25 And you reviewed this recently; correct?

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1 Axline; is that correct?

2 A. Yes. That appears to be the case.

3 Q. You agree with me; correct?

4 A. I think so, yes.

5 Q. And it is approximately -- it is 40 pages.
6 Does that sound about correct?

7 A. That's precisely correct.

8 Q. Fair enough.

9 Now your opinions with respect to the Jeans
10 study is on paragraphs 21, correct, in your report?

11 A. (Witness reviewing exhibit.) I'm trying to
12 find the reference list. I think that I've got --
13 There are two reference lists, so help me with this.
14 Page 40 includes an addendum.

15 Q. I'm talking about your actual opinions. I'm
16 looking at page 16.

17 A. Yes, yes, yes. But I'm looking at the
18 reference list and I'm trying to confirm that
19 reference number 37 cited there is the Jeans study.
20 Isn't that what you're asking me?

21 Q. No. I'm just saying your opinions --

22 A. I'm just looking for the --

23 Q. Okay.

24 A. -- Jeans article as cited in my list so I
25 can make sure that everything's correct.

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1 A. Yes.

2 Q. Is there any changes you'd like to make,
3 sitting here today?

4 A. No. That -- There is subsequently
5 information that has come available that supports my
6 opinion, but I wouldn't change this.

7 Q. I'm only talking about the Axline opinion
8 today.

9 A. I under --

10 No, I understand, but you're asking me about
11 my opinion.

12 Q. And let's be clear, here. It's my
13 understanding from counsel, and I'd like him to
14 stipulate, that -- that this deposition is based on
15 the Motion For Reconsideration as filed by the
16 defendants, and there'll be no new evidence other than
17 that was -- which was in the Motion For
18 Reconsideration based on your Axline study; is that
19 correct?

20 MR. GOSS: Right. So as far as Dr. Borak
21 is concerned, the citation in our motion to the
22 Axline report is the only thing we're going to rely
23 on from Dr. Borak. We're not going to supplement
24 anything for the motion from Dr. Borak.

25 BY MR. ASSAAD:

1 A. I don't hold myself out in the practice of
2 infectious disease medicine.

3 Q. With respect to the Jeans study, are you
4 aware of what percentage of the total population of
5 orthopedic surgeries came from the McGovern hospital?

6 A. I can guess, but I can't be sure, and I can
7 guess based upon averages. So I know, for example,
8 that the Jeans study included roughly, for example in
9 the first three years of the Jeans study there was
10 about 3600 infections, and --

11 Q. Surgeries.

12 A. Surgeries. That's what I meant, yes. Thank
13 you very much. 1.92 percent of infections. And when
14 I look at the rate of infections at the McGovern
15 hospital from the McGovern paper, there were 32 over
16 20 months. And I can look at the surgeries that they
17 did; they did 1,066 cases in 20 months. And so that
18 would have been -- for the 20 months that was included
19 in the Bair Hugger period of the McGovern study, it
20 would have been 53 cases a month, on average. And
21 Jeans cites a hundred a month on average for the three
22 hospitals with the added inclusion of perhaps
23 non-elective surgeries. I don't know what percentage
24 that makes.

25 Q. Okay. And that's for the prescreening

1 -- I'm trying to see. I may not have actually
2 calculated that particular number, but I have accepted
3 the 53 as an average a month for the McGovern. It's
4 somewhere in that range.

5 Q. Fifty-three a month for McGovern.

6 A. I think so.

7 Q. So that would be about 600 a year.

8 A. Yes.

9 Q. So over the four years it would be about
10 2400.

11 A. If it was flat, yes.

12 Q. Okay. So that means it's about 30 percent.

13 A. I'm looking about 50 percent. The rate
14 after 2010 seems to have increased at the other
15 hospitals.

16 Q. At the other hospitals, correct.

17 A. Yes.

18 Q. So McGovern would have been a much smaller
19 percentage, the McGovern hospital.

20 A. Might have been. I -- The problem here is
21 that Jeans includes data that I don't -- for which I
22 don't have corresponding numbers for any of the
23 hospitals.

24 Q. Okay. So we would just be speculating.

25 A. Yeah. Just -- I -- You know. I mean, pick

1 group; correct?

2 A. That's right.

3 Q. So you would agree probably one third of the
4 -- or half of the prescreening group came from the
5 McGovern hospital.

6 A. I think slightly more, but yes.

7 Q. Okay.

8 A. I'm guessing.

9 The reason I'm guessing is because we don't
10 know, from the McGovern study, what was the numbers of
11 cases specifically during the first 18 months of the
12 Jeans study.

13 Q. We'll get to that. I understand where
14 you're going with that.

15 A. Okay.

16 Q. I understand that.

17 A. But I just want to be clear.

18 Q. Okay.

19 A. I don't want you to think that I'm just
20 guessing. I mean I --

21 Q. What about with respect to the
22 post-screening group?

23 A. The only data that I have that I have seen
24 in press, besides Jeans, is McGovern, and McGovern
25 came to about, whatever the number was, they report a

1 a number, I'll...

2 Q. We'd just be guessing. Fair enough.

3 What percentage of the infections that are
4 -- that are in the Jeans study in Table 3 --

5 Let me pull out the study and mark it as an
6 exhibit.

7 A. Fine. Thank you.

8 You mark it, and if you don't mind, I have
9 given you a color copy of my article and I'm going to
10 look at my article --

11 Q. Fair enough.

12 A. -- because there are some typos in the
13 original and I just, I want to avoid some of the
14 mistakes.

15 MR. ASSAAD: Let's mark as Exhibit Number 3
16 the Jeans study.

17 (Borak Exhibit 3 marked for
18 identification.)

19 BY MR. ASSAAD:

20 Q. And going back to --

21 Can we switch, because you're supposed to
22 hold the one that has the marking. Or did you already
23 write on that?

24 A. It's just -- You've got it, it's just the
25 colors a little bit -- I feel --

Q. Oh, he has the original?

A. I have the original and I color copied it for you.

Q. Fair enough. Fair enough.

Before I begin, you performed no calculations with respect to the Jeans data; correct?

A. I did some very informal calculations mainly in my head.

Q. In your head, but you didn't write any of it down.

A. No.

Q. What informal calculations did you do?

A. I looked at the origins of the numbers in the Jeans papers, and I looked to see what -- you'll see along Table 3, I just looked to see what were the changes, percentage-wises, you know. I also did some working back on the basis of some other estimates but not on the Jeans paper, it was on the Augustine, which we're not talking about.

Q. Did you ever consider that the data in the Jeans study, one of the confounders would be the McGovern study and the role of the Bair Hugger?

A. I was aware of the issue, but it doesn't speak to me.

Q. Well you understand that part of the data

based on looking at Table 3, if there was a change in the deep joint infection rates in the Jeans study?

A. One can't specifically determine that.

Q. So according to the Jeans study you can't determine if there was a change in the deep joint infection rates between the pre-screening group and the post-screening group; correct?

A. I don't have data on the deep joint infection rate in either of those time periods.

Q. So you can't determine if there was a reduction in the infection rates -- in the deep joint infection rates as a result of the MSSA screening protocol; correct?

A. Yes. Nor did I ever suggest that there was.

Q. You are aware that there was no reduction in infection rates in the Jeans study as it relates to non-MSSA infections; correct? Significant reduction.

A. You're talking about statistically significant.

Q. Yes.

A. However, the hip data show a nonsignificant but an almost 30 percent decrease in infection rate in the non-MSSA group. Okay. And they show significant decreases in the MSSA. So the only thing you're pointing to is one, the non-MSSA for the knees, and

set in the Jeans study includes time of when nonforced-air warming, patient-warming device was used in some patients.

A. I'm aware that Bair Hugger was used during one part of the McGovern study and not during the other half, and I didn't know what was going on in the other two hospitals.

Q. Okay.

A. So yes, it could have been.

Q. So you agree with me that the fact that the Bair Hugger was not used during the time period could be a confounder in the Jeans study.

A. It was potentially a confounder.

Q. Okay. Did you do any calculations to determine if it was a confounder?

A. I'm sorry?

Q. Did you do any calculations to determine if it was a confounder?

A. I couldn't have done that because there were no data on that.

Q. Now with respect to Table 3, you've mentioned before that the Jeans study deals with both deep joint and superficial wound infections; correct?

A. That's correct.

Q. Do you know if there was a change, just

that does not show a decrease.

Q. Do you know why that is?

A. I don't know but, you know, there was this very strange thing that came out in the McGovern paper where they found that they had a decreased frequency of knee infections compared to hip, which was contrary to what the world generally reports. And so it may be that this was just a reflection of regression to the mean. I don't know.

Q. You're speculating.

A. I'm speculating.

Q. And in fact the authors did not know the significance of that either, correct, of the Jeans study?

A. The Jeans study, I don't think they talked about it. I think what they were saying in the Jeans study --

Q. They say on page 4 of the Jeans study, --

A. I don't have a page 4.

Q. Page 408 of Exhibit --

MR. GOSS: Three.

Q. -- 3 --

A. Yes.

Q. -- they talk about the knee replacement cohort --

1 A. Which paragraph are you looking at?

2 Q. The top, first line.

3 A. Oh. Knee replacement cohort did not have a
4 positive proportionate benefit from the screening
5 programme, and they -- there was no significant
6 change. I understand that.

7 Q. And they say: "This is difficult to
8 explain, we have not come across anything in the
9 literature to prove why MSSA screening and
10 decolonisation would be more effective in hips than in
11 knees"; correct?

12 A. Yes. Understood.

13 Q. So they don't have an explanation for it.

14 A. They don't have an explanation.

15 Q. Okay.

16 A. My effort was that they had had otherwise
17 inexplicably low rates of knee infection in the
18 McGovern study during the first half and overall, and
19 this may have simply reflected a regression back to
20 the mean, but I don't know.

21 Q. Now you have access to the McGovern data;
22 correct?

23 A. I have access to the exhibits from
24 depositions that were done by some of the McGovern
25 authors, but I -- and I've looked at some of that. I

1 have not done analyses of them, I've relied largely on
2 the specific analyses by Dr. Holford.

3 Q. Now we could agree, doctor, that we know for
4 certain that in the McGovern data set that the Bair
5 Hug -- there's a time period where the Bair Hugger was
6 not used; correct?

7 A. I'm sorry. Say that again. I think I
8 agree, but --

9 Q. We know for certain in the McGovern data
10 that there was a time period that the Bair Hugger was
11 not used.

12 A. I agree. That is true.

13 Q. Okay. We don't know with respect to the
14 other two hospitals; correct?

15 A. Yes, that is also true.

16 Q. Okay. And you've read Reed's deposition;
17 correct?

18 A. Yes. Not in some time, but yes.

19 Q. Assuming that the HotDog was only used at
20 the McGovern hospital and not the other two hospitals,
21 did you ever consider pulling out the McGovern data
22 from the Jeans study data to determine whether or not
23 there is a change in infection rates?

24 A. I didn't have the Jeans data.

25 Q. Well you have Table 3; correct?

1 A. Yes, but this subsumes deep and superficial
2 infections at a time period for which I didn't have
3 data.

4 Q. Okay. Well we know we -- like --

5 But you could pull out the deep joint
6 infections in the McGovern data from the Jeans study;
7 correct?

8 A. Only if Jeans had explained what happened
9 before July of 2008 and what happened after. And
10 since those are pooled, I don't know. It can't be
11 done.

12 Q. You're not aware that -- Strike that.

13 You're aware that in McGovern they did not
14 use data before July 1st, 2008.

15 A. Say that again.

16 Q. They did not use data before July 1st, 2008;
17 correct?

18 A. In the McGovern report. Yes, I'm aware of
19 that.

20 Q. And you read Reed's deposition and he gave
21 an explanation for that; correct?

22 A. Yes, I did.

23 Q. Because there wasn't continuous data, they
24 did data just on a quarterly basis. Do you recall
25 that?

1 A. I don't remember the quarterly thing, but I
2 remembered he said that the data -- that they
3 implemented, he said, the surveillance program in July
4 of 2008 or thereabouts, and only used the data
5 subsequent to that. That was why I found the Jeans
6 statement so remarkable, when the Jeans paper says
7 that that was wrong. I -- I found that to be the most
8 surprisingly thing in the Jeans paper, frankly.

9 Q. Okay.

10 A. It doesn't have to do with MSSA.

11 Q. So you're -- you are disagreeing with Dr.
12 Reed with respect to his opinion that data before July
13 1st, 2008 was unreliable.

14 A. Let me explain. The answer is yes.

15 Q. So you disagree with that.

16 That's all I need. That's all I need.

17 A. Yeah. But the Jeans paper disagrees.

18 Q. Is there anything that states that they took
19 data from the McGovern hospital in the Jeans paper
20 prior to July 1st, 2008?

21 A. Absolutely.

22 Q. Where does it say that? Where does it
23 say --

24 A. One --

25 Q. Where does it say, doctor --

1 Listen. Where does it say specifically that
2 -- that all three hospitals had data from 2007 to
3 2010?

4 MR. GOSS: Gabriel, you don't have to
5 point. He'll answer your question.

6 Q. Show me that, doctor.

7 A. Well the statement says, infection
8 monitoring has been performed with complete data
9 available from prior to screening program 1st January
10 2007 to 31 December 2009, and after its introduction
11 this study is a retrospective review of this
12 prospectively collected data.

13 If they did not have data for part of that
14 time in one of the hospitals, they should have said
15 so.

16 Q. They said "available." "Available data."
17 Correct?

18 A. Complete data is available. No, no.
19 Complete data was accessible.

20 Q. But you don't know; do you, doctor?

21 A. I think that you're attributing a
22 deceitfulness to these authors which they don't
23 deserve from you, sir.

24 Q. I'm not saying they're deceitful. But they
25 might have pulled data from the other two hospitals

1 Q. I mean we don't know what date range each of
2 the hospitals provided in the Jeans study, do we?

3 A. I'm sorry, sir. Are you telling me that you
4 think that the Jeans data are so corrupt that they
5 can't be relied upon?

6 Q. I'm not saying that.

7 A. Well that's what you just implied.

8 Q. You're making the assumption that all three
9 hospitals produced data from January 1st, 2007 to --
10 to August 2014; aren't you?

11 A. I think that's a reasonable interpretation
12 of the statement that I just read to you.

13 Q. It's an interpre --

14 But you're not exactly sure; are you?

15 A. It wouldn't have occurred to me that it was
16 not the case because --

17 Q. Answer my question.

18 A. -- any res --

19 Q. Are you sure about --

20 A. I'm sure about very few things in life.

21 Q. Okay. Is it possible that with respect to
22 the Jeans study -- Jeans study, they only started the
23 Wans -- they used the Wansbeck data starting -- or the
24 McGovern data from July of 2008?

25 MR. GOSS: I think he already answered

1 from 2007, and from Wansbeck in January of 2 -- July
2 of 2008.

3 A. That would be --

4 Q. I don't know. Do you know?

5 A. I don't know, but that --

6 Q. Okay.

7 A. -- would be objectively deceitful if they
8 said they had complete data and it turned out they
9 didn't have complete data.

10 Q. It would be nice to take their deposition,
11 though, and ask these questions, wouldn't it?

12 MR. GOSS: Object to form.

13 A. I am not an attorney, sir.

14 MR. GOSS: You don't have to answer that.

15 Q. But wouldn't you want to -- I mean, these
16 are the types of questions that you could ask someone
17 with respect to what exact data did you use, what --
18 where is the data set, to understand the Jeans study
19 more; correct?

20 MR. GOSS: Object to form.

21 A. I think the questions are askable.

22 Q. Okay. We don't know some of these answers
23 for the Jeans study; correct?

24 MR. GOSS: Which questions are you talking
25 about?

1 that, but if you have a different answer, go ahead.

2 A. I can only say from the prospective of my
3 years in this field in medicine and in science, and
4 from having been a member of five different editorial
5 boards, that if somebody had in fact written this
6 statement and had concealed that one of the hospitals
7 had incomplete data, that that would have been grounds
8 for a retraction.

9 Q. Well you were just accusing Dr. Reed that --
10 who's an author of this study -- that he truncated the
11 McGovern study and did something deceitful; aren't
12 you?

13 A. I -- I believe that this paper --

14 Q. That's not my question.

15 A. -- contradicts --

16 Q. My question is:

17 MR. GOSS: Wait. Wait.

18 Q. Are you accusing Dr. Reed of doing something
19 deceitful by truncating the McGovern study?

20 A. Sir, sir --

21 MR. GOSS: Time out. Whoa, whoa, whoa.
22 Time out.

23 A. Sir, if you can't lower your voice and talk
24 like a gentleman, you'll make it very uncomfortable
25 here.

1 inconsistency.

2 A. I can't prove it.

3 Q. Okay. You can't prove it.

4 A. I can't prove it.

5 MR. ASSAAD: Okay. Let's take a break.

6 THE REPORTER: Off the record, please.

7 (Recess taken from 12:10 to 12:14 p.m.)

8 BY MR. ASSAAD:

9 Q. Doctor, going to Exhibit Number 3, your --
10 the Jeans study.

11 A. Yes, sir.

12 Q. You agree with me that Table 3 is a
13 univariate analysis of infection rates between the pre
14 and post screening MSSA protocols; correct?

15 A. I don't think it's univariate analysis. I
16 think it's just crude data.

17 (Interruption by the reporter.)

18 Q. If you go to page 407, you actually circle
19 "univariate --

20 A. Yes.

21 Q. -- analysis" on the bottom paragraph.

22 A. Yes.

23 Q. So you agree with me that Table 3 is a
24 univariate analysis.

25 A. No, sir.

1 Q. When it says, the universe -- univariate
2 analysis was shown to significantly reduce overall
3 infection rate P of .03, did I read that correctly?

4 A. I see. You're saying that the p-value is
5 the result of the univariate, and I was just looking
6 at the crude numbers there.

7 Yes, you're right. The p-values were
8 calculated I assume as a univariate analysis.

9 Q. Okay. And so you agree with me that this
10 Jeans study, Table 3, is a observational study that
11 does the univariate analysis, according to the paper.

12 A. Allow me. I appreciate your question, I
13 just would like to answer it properly. (Witness
14 reviewing exhibit.)

15 I see -- Help me, please. I see in this
16 discussion only a discussion of multivariate.

17 Q. "While multivariate analysis show that MSSA
18 screening programme was a significant factor in
19 preventing MSSA infection, a univariate analysis was
20 shown to significantly reduce overall infection rate"
21 P -- with a P value of .03.

22 A. And help me. I feel like an idiot. Maybe
23 it's only my mind which is going. Which line?

24 I'm sorry. Are you talking in this
25 paragraph [indicating]?

1 Q. No. [Indicating.]

2 A. Ahh, I'm sorry. I'm sorry.

3 (Witness reviewing exhibit.) Yes, I read
4 that sentence. What is your question about it, sir?

5 Q. That Table 3 is a -- is -- of the Jeans
6 study is an observational study showing a univariate
7 analysis.

8 A. And the answer is I actually don't know. I
9 see the .03 applies as well, but I also see that there
10 are data in the paragraph under regression analysis
11 where some of the numbers seem to be similar.

12 Q. I --

13 A. I -- I don't have a...

14 If it matters to you, I mean I don't know
15 for sure that this is all univariate, but I'm willing
16 to accept, for the moment, to let you go on and ask me
17 a question. I'm not trying it --

18 This is hardly the place I want to disagree
19 with you, sir.

20 Q. Okay. Well you agree with me that based on
21 the Jeans study they did a univariate analysis
22 according to the study.

23 A. You would always do a univariate analysis to
24 determine what are the significant -- or -- or the
25 concerned risk factors, and then you would put the

1 concerned ones into your multivariate.

2 Q. Okay. And they did a p-value of .03 which
3 corresponds to the p-value of the total infection rate
4 change in Table 3; correct?

5 A. Yes. I see that.

6 Q. Okay. You're not -- Strike that.

7 The McGovern study has not been retracted;
8 correct?

9 A. To the best of my knowledge it has not been
10 retracted.

11 Q. Okay. And you are aware that the McGovern
12 study has been cited multiple times in literature
13 after the Jeans study.

14 A. After the Jeans study?

15 Q. Yes.

16 A. I don't know about multiple times.

17 Q. Are you aware that the International
18 Consensus of Orthopedic Surgeons on Periprosthetic
19 Joint Infections cited to the McGovern study in -- in
20 the fall of this year?

21 A. Yes. I believe that the chapter written by
22 Dr. Reed referred to it and raised the fact that there
23 were lots of questions being raised about the McGovern
24 study.

25 Q. But he also --

1 He didn't say that it was unreliable any
2 more, did he?

3 A. No. He didn't specifically say that.

4 Q. And in fact you're aware that 3M is -- and
5 Dr. Reed are pursuing a study with respect to this
6 issue of forced-air warming and non-forced-air warming
7 currently; correct?

8 A. Yes. I am aware of a pilot study that was
9 done, but which I am apparently not supposed to talk
10 about today.

11 Q. Oh, so you're aware of the pilot study.

12 A. I am aware of the RIIiOs document.

13 Q. Do you understand information about the
14 RIIiOs study?

15 A. What do you mean by "understand
16 information"?

17 Q. Besides what's in the document that you
18 produced, are you aware of any other information?
19 What are you not supposed to talk about today?

20 A. I -- My impression was you didn't want me to
21 talk about anything that happened subsequently to the
22 Axline.

23 Q. Okay. I understand that.

24 But is there anything about --

25 Do you know anything about the status of the

1 some of these patients continued to be positive for
2 MSSA despite treatment is unknown and of course
3 whether this contributed to some MSSA infection in the
4 post screening program cohort is difficult to exclude
5 or confirm."

6 Did I read that correctly?

7 A. Yes, you read that correctly.

8 Q. So in the Jeans study they do not know what
9 percentage of the patients that went through the MSSA
10 protocol actually were eradicated of MSSA at the time
11 of surgery; correct?

12 A. Yes. I think that's what that means.

13 Q. Okay. In the --

14 Prior to January 1st, 2010 --

15 A. Prior to January 1st, 2010.

16 Q. The Jeans study. Are you aware of any MS --
17 MSSA eradication or decolonization measures that were
18 done in any of the patients of that group?

19 A. In -- In -- I'm sorry. Are we talking --

20 Q. In the Jeans study.

21 A. In the Jeans study.

22 Q. Yes.

23 A. My understanding is that it was introduced
24 as a system policy.

25 Q. As a system policy; correct?

1 RIIiOs study?

2 A. The only thing I know about the RIIiOs study
3 that would have been relevant was the statement which
4 says --

5 Q. I'm trying to hurry up here, doctor. Is
6 everything you know about the RIIiOs study in the
7 article you produced?

8 A. This? Yes.

9 Q. Okay. That's all I need to know. I
10 don't -- I have a limited amount of time, so.

11 Now with respect to the Jeans study, sitting
12 here today you are not aware of what percentage of the
13 patients that went through the MSSA screening process
14 were eradicated of MSSA; correct?

15 A. No. I've seen elsewhere that Reed has cited
16 numbers, but I haven't seen that specific number here.

17 Q. And specifically it states in the Jeans
18 study, you agree, that they never retested after they
19 started to see whether or not MSSA was present after
20 they went through the MSSA protocol; correct?

21 A. I don't specifically remember it, but I --
22 I'll accept it, or point it out and I'll look at it
23 really quickly.

24 Q. If you look at the first full paragraph on
25 page 408, the last four lines, it states: "Whether

1 A. Yes.

2 Q. But some --

3 But we're not sure if anyone went through
4 the eradication or decolonization prior to January
5 1st, 2010; right?

6 A. I didn't see anything about that.

7 MR. GOSS: For MSSA; right?

8 Q. For MSSA. Correct?

9 A. Correct. I think that's right.

10 Q. Some of them could have gone through the
11 MSSA eradication or decolonization; correct?

12 A. Could have been.

13 Q. And that would be a confounder; correct?

14 A. It's not specifically what one would call a
15 confounder, it might be an effect modifier.

16 Q. Okay. It might modify the data.

17 A. Modify the apparent effect.

18 Q. So just so I understand it clearly, sitting
19 here today we don't know whether or not the Jeans
20 study, the MSSA protocol, had an effect on superficial
21 wound infections, deep joint infections or both;
22 correct?

23 A. Yes, that's correct.

24 Q. Okay. And McGovern dealt with just deep
25 joint infections; correct?

1 A. Yes.

2 Q. Okay. So it's quite possible, without
3 having the raw data in front of us, that the entire
4 effect of the MSSA protocol was just on superficial
5 wound infections.

6 A. Anything's possible, but there are other
7 publications that suggest otherwise, including from
8 Dr. Reed.

9 Q. Okay. But based on the Jeans study --

10 A. Purely on the Jeans study, he does not
11 differentiate.

12 Q. Okay. And therefore, the reduction in
13 infection rates could be solely a reduction in
14 superficial wound infection rates; correct?

15 A. It's possible.

16 Q. We don't know; correct?

17 A. We don't know.

18 Q. Okay. I understand that you and Dr. Holford
19 have opinions on the McGovern study, but I want to
20 take the McGovern study as what -- its face value and
21 what it states in the paper. Correct? You un --

22 A. Repeat the first half of that.

23 Q. You have opinions about the McGovern study
24 and the data and the subset data of McGovern, and --

25 You have many opinions about the McGovern

1 infection rate with the MSSA protocol -- Withdraw
2 that.

3 The overall infection rate with respect to
4 the total infection rate in Table 3 went from 1.92
5 percent to 1.41 percent; correct?

6 A. I'm sorry. We're looking at the Jeans
7 study?

8 Q. Yes.

9 A. And you're looking at Table 3?

10 Q. Yes.

11 A. And we are looking at 1.92 percent in the
12 pre-screening group, and 1.41 percent in the
13 post-screening group, correct.

14 Q. And by the way, just as a overview, on the
15 first page of Exhibit 3 the authors indicate that only
16 about 24.6 percent of infections are MSSA; correct?
17 Bottom right-hand paragraph.

18 First page.

19 A. No, I see that. I'm looking at what their
20 references are. (Witness reviewing exhibit.)

21 Well they're quoting numbers that they're
22 taking from two papers, and as we sit here today I
23 don't know where those papers were prepared and what
24 they reflect, but they are general background. I --
25 This does not speak about the rates of such infections

1 study.

2 A. Yes.

3 Q. I want to focus just on what's actually
4 written in the McGovern study; okay?

5 A. We can do that.

6 Q. Okay. We know that the McGovern study shows
7 an odds ratio of 3.8 reduction in infection rates
8 between the Bair Hugger period and the non-Bair Hugger
9 period; correct?

10 A. If you stick only to the four corners of the
11 McGovern paper and ignore the admissions during their
12 earlier depositions which said that those numbers
13 actually are wrong.

14 We know that there were other cases and some
15 were wrongly tabulated so the 3.8 is not correct. But
16 if you ask me to ignore their previous testimony and
17 stick to only the four corners of this paper which we
18 know to have errors in it, then yes, you're right.

19 Q. Okay. It's a 3.8 odds ratio; correct?

20 A. In the incorrectly prepared paper, yes.

21 Q. Four corners of the McGovern study. Let's
22 just stick to the four corners --

23 A. Only in the four corners.

24 Q. -- of the McGovern.

25 And you agree with me that in the overall

1 necessarily in Northumbria, but I think those may be
2 fair numbers. I just am telling you I don't -- I
3 don't know what they mean exactly.

4 Q. But that's --

5 Whatever study they're looking at, I mean
6 they're saying in about 25 percent, give or take, of
7 infections are due to MSSA.

8 A. What they're saying is about a quarter of
9 them are --

10 Q. Okay.

11 A. -- and I have no reason to disagree, but I
12 don't have any reason to specifically --

13 Q. Okay.

14 A. -- to embrace it.

15 Q. So you agree with me that the MSSA protocol
16 would only apply to 25 percent to reduce that 25
17 percent of infections in that subset of patients;
18 correct?

19 A. Yes, presumably. Let me rephrase. If --
20 You're asking me do I think that the MSSA protocol
21 would have impacted the non-MSSA infections, and the
22 answer is no, I wouldn't have expected it.

23 Q. Okay. So would you agree with me that the
24 Jeans study, if you take it down to what it's really
25 saying, is the Jeans study, doing an MSSA protocol,

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1 The Jean paper relates to MSSA --

2 Q. There's no question pending, sir.

3 A. Sorry.

4 Q. This was cited in 2019 --

5 This article was published in 2019. Do you
6 see that?

7 A. I saw the date on it, yes.

8 Q. Okay. And that's after the Jeans study;
9 correct?

10 A. After it was published, that's correct.

11 Q. Okay. And it's the same author as the Jeans
12 study and the McGovern study, Dr. Reed; correct?

13 A. Dr. Reed, correct.

14 MR. GOSS: Does it talk about Jeans?
15 Because I thought this was going to be about Jeans
16 today.

17 MR. ASSAAD: No. I'm telling him that the
18 author that he's calling -- that he's saying that the
19 McGovern's unreliable, that he's still citing to
20 McGovern in 2019 even after the Jeans study.

21 MR. GOSS: All right. Well I think this is
22 outside of the scope for today and this is more for
23 the next deposition but, you know, you got your time
24 -- you got your time and you may explore it.

25 BY MR. ASSAAD:

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1 what he's answering questions about.

2 MR. ASSAAD: He can take all the time he
3 wants. I'm just not going to put it on my time.

4 MR. GOSS: Right. Let's go ahead. You're
5 comfortable with that?

6 THE WITNESS: I'm comfortable till I hear
7 the question that I'm uncomfortable with.

8 MR. GOSS: Yeah. So we'll take a break if
9 we need to, but for now let's see where you're going.

10 BY MR. ASSAAD:

11 Q. My point is is that Dr. Reed cites to the
12 McGovern study in 2019.

13 A. Yes, he did.

14 Q. Okay. So you agree with me that if Dr.
15 McGovern was under the impression that the Jeans study
16 altered the findings of the McGovern study, that a
17 competent researcher like Dr. McGovern would not be
18 citing the findings of the McGovern study after the
19 Jeans study.

20 MR. GOSS: Do you mean Dr. Reed?

21 Q. Or Dr. Reed. I'm sorry.

22 A. Sir, I've already told you that I'm curious
23 about Dr. Reed's consistency, but I -- I can tell you
24 he has done exactly what you said he did. I don't
25 know what was in his mind.

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1 Q. Doctor, it says: Within a laminar flow
2 theatre, McGovern et al compared forced-air warming
3 devices to air free conductive fabric warming blankets
4 and showed that they were associated with
5 substantially higher numbers of simulated particles
6 and over the -- over the operative field and
7 substantially higher rates of postoperative PJI.

8 Did I read that correctly?

9 A. You read that correctly.

10 MR. GOSS: So since you haven't seen this
11 before, take your time to read it and look at the
12 sources if you need to --

13 Q. Do you want to read it?

14 A. Sure.

15 MR. GOSS: -- if you need to in order to
16 answer the questions.

17 MR. ASSAAD: Let's take a break.

18 MR. GOSS: No, no. You --

19 A. No, no. No reason to take a break.

20 MR. ASSAAD: Well I'm not going to take my
21 time, which is limited, for him to read an entire
22 article.

23 MR. GOSS: Well, but again you're -- you're
24 not -- this is not about Jeans. He's -- I'm just
25 telling him he needs to make sure that he understands

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1 Q. And are you aware that Dr. Reed also cites
2 Dr. Elghobashi's paper in this article?

3 MR. GOSS: Do you need to see where he
4 does?

5 Q. Do you know who Dr. Elghobashi is?

6 A. Yes.

7 Q. Okay. If you go to cite 50.

8 A. Cite 50?

9 Q. Yes.

10 I represent to you that He X, Karra, and
11 Pakseresht is a published article of Dr. Elghobashi.
12 Were you aware of that Dr. Reed is now citing to Dr.
13 Elghobashi's study that he did in this case?

14 A. I see the statement.

15 Q. Okay. And I want to read the last sentence
16 here. "Therefore, forced-air warmers could be
17 considered detrimental to effective LAF and has been
18 recognized in National Institute For Health and Care
19 Excellence guidelines on peri-operative warming in
20 orthopedic surgery. Recommendations for effective LAF
21 use are shown in Table 2."

22 Are you familiar with the National Institute
23 For Health and Care Excellence guidelines?

24 A. When were these published? (Witness
25 reviewing exhibit.)